



Docket No. MCP-274

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : LUBER et al.

Serial No. : 09/966,493

Art Unit: 1615

Filed : September 28, 2001

Examiner: Robert M. Joynes

For : IMMEDIATE RELEASE TABLET

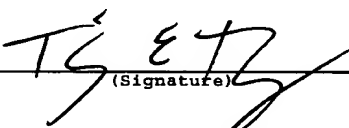
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June 25, 2004

(Date of Deposit)

Timothy E. Tracy

(Name of applicant, assignee, or Registered Representative)



(Signature)

June 25, 2004

(Date of Signature)

Commissioner for Patents  
P.O. Box 1450  
Washington, D.C. 20231

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This copy is supplemental to the Information Disclosure Statements mailed on January 9, 2002 and May 27, 2003.

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this

information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☐ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e)  
(attached); or

☐ Please charge Deposit Account No. 10-  
0750/ / the fee of \$180.00 as set forth  
in §1.17(p).

☒ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☒ Please charge Deposit Account No. 10-0750/MCP-274/TT the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☐ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not

enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☐ There are no listed references which are not in the English language.

☒ The relevance of those listed references which are not in the English language is as follows: DE 19954420 A1, EP 0239983 B1, and WO 99/02136 A1 have English language abstracts only; NL 8602556 has an English language translation attached.

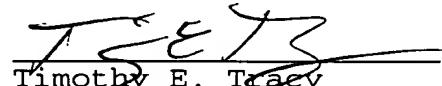
☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

Copies of the references listed on the search report(s) are included except for those previously cited in an IDS mailed .

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to  
Deposit Account No. 10-0750/MCP-274/TT. This form is submitted  
in triplicate.

Respectfully submitted,

  
Timothy E. Tracy  
Reg. No. 39,401  
Attorney for Applicants

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DATED: June 25, 2004  
Customer No. 000027777



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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 7

<i>Application Number</i>	09/966,493
<i>Filing Date</i>	September 28, 2001
<i>First Named Inventor</i>	Joseph R. Lubner
<i>Group Art Unit</i>	1615
<i>Examiner Name</i>	Robert Joynes
<i>Attorney Docket Number</i>	MCP-274

### U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		582,438		J. Scheidler	05-11-1897	
		599,865		E.L. Richards	03-01-1898	
		2,307,371		H.B. Hileman	01-05-1943	
		2,996,431		R.H. Barry	08-15-1961	
		3,085,942		Louis Magid et al.	04-16-1963	
		3,146,169		D. Stephenson et al.	08-25-1964	
		3,627,583		John P. Troy et al.	12-14-1971	
		3,726,622		Georges D. DeTroyer et al.	04-10-1973	
		3,804,570		Gunter Hoschele et al.	04-16-1974	
		3,832,252		T. Higuchi et al.	08-27-1974	
		4,139,589		Monique Beringer et al.	02-13-1979	
		4,230,693		Henry J. Izzo et al.	10-28-1980	
		4,271,206		Harry F. Fariel et al.	06-02-1981	
		4,273,793		Harry F. Fariel et al.	06-16-1981	
		4,292,017		Wallace A. Doepel	09-29-1981	
		4,362,757		Andy C. Chen et al.	12-07-1982	
		4,372,942		Paul A. Cimiluca	02-08-1983	
		4,392,493		Halbe J. Niemeijer	07-12-1983	
		4,425,332		Michael H. James	01-10-1984	
		4,473,526		Eugen Buhler et al.	09-25-1984	
		4,518,335		Vimal K. Pujari	05-21-1985	
		4,528,335		Larry M. Selby et al.	07-09-1985	
		4,533,345		John A. Louw	08-06-1985	
		4,544,345		Eugen Buhler et al.	10-01-1985	
		4,569,650		Hans Kramer	02-11-1986	

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 2 of 7

<b>Application Number</b>	09/966,493
<b>Filing Date</b>	September 28, 2001
<b>First Named Inventor</b>	Joseph R. Lubert
<b>Group Art Unit</b>	1615
<b>Examiner Name</b>	Robert Joynes
<b>Attorney Docket Number</b>	MCP-274

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		4,749,575		Avner Rotman	06-07-1988	
		4,762,719		Mark Forester	08-09-1988	
		4,781,714		J.B. Eckenhoff et al.	11-01-1988	
		4,813,818		Michael Sanzone	03-21-1989	
		4,820,524		Norbert I. Berta	04-11-1989	
		4,929,446		Raymond A. Bartolucci	05-29-1990	
		4,965,027		Nobuyuki Takahashi	10-23-1990	
		4,980,169		Alfred Oppenheimer et al.	12-25-1990	
		5,002,970		George A. Eby, III	03-26-1991	
		5,059,112		Marianne Wieser	10-22-1991	
		5,089,270		Douglas B. Hampton et al.	02-18-1992	
		5,145,868		Andreas von Sprecher et al.	09-08-1992	
		5,146,730		Hani Sadek et al.	09-15-1992	
		5,188,840		Yoshimitsu Iida et al.	02-23-1993	
		5,200,191		Don Steele et al.	04-06-1993	
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		5,229,164		Heinrich Pins et al.	07-20-1993	
		5,368,863		James B. Eckenhoff et al.	11-29-1994	
		5,391,378		Richard Sanderson	02-21-1995	
		5,405,642		Paul M. V. Gilis et al.	04-11-1995	
		5,415,868		Floyd S. Smith et al.	05-16-1995	
		5,436,026		Norbert I. Berta	07-25-1995	

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 7

Application Number	09/966,493
Filing Date	September 28, 2001
First Named Inventor	Joseph R. Lubert
Group Art Unit	1615
Examiner Name	Robert Joyntes
Attorney Docket Number	MCP-274

### U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		5,459,983		Hani Sadek et al.	10-24-1995	
		5,464,631		Charles E. Hoover et al.	11-07-1995	
		5,511,361		Erich W. Sauter	04-30-1996	
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		5,578,336		Woodrow C. Monte	11-26-1996	
		5,609,010		Erich W. Sauter	03-11-1997	
		5,614,207		Manoj N. Shah et al.	03-25-1997	
		5,679,406		Norbert I. Berta	10-21-1997	
		5,681,584		Louis Savastano et al.	10-28-1997	
		5,711,961		Alberto Reiner et al.	01-27-1998	
		5,795,588		Erich W. Sauter	08-18-1998	
		5,807,579		Zalman Vilkov et al.	09-15-1998	
		5,824,338		Richard L. Jacobs et al.	10-20-1998	
		5,827,874	A	Meyer et al.	10-27-1998	
		5,830,501		Liang C. Dong et al.	11-03-1998	
		5,830,502		Liang C. Dong et al.	11-03-1998	
		5,834,035		Michio Osada et al.	11-17-1998	
		5,837,301		Robin A. Arnott et al.	11-17-1998	
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		5,871,781		Garry L. Myers et al.	02-16-1999	
		5,942,034		Jeffrey D. Brehant et al.	08-24-1999	
		5,997,905		Daniel McTeigue et al.	12-07-1999	
		6,001,391	A	Zeidler et al.	12-14-1999	
		6,103,257		Keith Nisonoff	08-15-2000	
		6,117,479		John E. Hogan et al.	09-12-2000	

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 4 of 7

<b>Application Number</b>	09/966,493
<b>Filing Date</b>	September 28, 2001
<b>First Named Inventor</b>	Joseph R. Luber
<b>Group Art Unit</b>	1615
<b>Examiner Name</b>	Robert Joynes
<b>Attorney Docket Number</b>	MCP-274

**U.S. PATENT DOCUMENTS**

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		Number	Kind Code <sup>2</sup> (if known)			
		6,120,802	A	Breitenbach et al.	09-19-2000	
		6,149,939		Matthew A. Strumor et al.	11-21-2000	
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		6,350,398		Jorg Breitenbach et al.	02-26-2002	
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		6,433,015	B1	Meyer	08-13-2002	
		6,727,213	B2	Waschenbach et al.	04-27-2004	
		6,730,646	B1	Waschenbach et al.	05-04-2004	
		2001/0001280	A1	Liang-Chang Dong et al.	05-17-2001	
		2002/0028240	A1	Toyohiro Sawada et al.	03-07-2002	
		2003/0203016	A1	Dr. Suwelack Skin & Health Care AG	10-30-2003	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
		DE	19954420	A1	LTS Lohmann Therapie- Systeme AG	05-31-2001	NOTE: English language abstract only	
		EP	0 088 556	B1	Sumitomo Chemical Company Ltd.	09-14-1983		
		EP	0 239 983	B1	Boehringer Ingelheim International GmbH	10-07-1987	NOTE: English language abstract only	

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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet 5 of 7

<b>Application Number</b>	09/966,493
<b>Filing Date</b>	September 28, 2001
<b>First Named Inventor</b>	Joseph R. Luber
<b>Group Art Unit</b>	1615
<b>Examiner Name</b>	Robert Joynes
<b>Attorney Docket Number</b>	MCP-274

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>				
		EP	0 294 993	B1	Pfizer Inc.	12-14-1988		
		EP	0 387 885	B1	Bristol-Myers Squibb Company	09-19-1990		
		EP	0 455 599	A1	Warner-Lambert Company	11-06-1991		
		EP	0 481 547	A1	Unilever PLC & Unilever NV	04-22-1992		
		EP	0 531 524	B1	SS Pharmaceutical Co. Ltd.	03-17-1993		
		EP	0 572 731	A1	The Procter & Gamble Company	12-08-1993		
		EP	0 619 854	B1	V. Kann Rasmussen Industri A/S	03-04-1998		
		EP	0 646 650	A2	Fuisz Technologies Ltd.	04-05-1995		
		EP	0 646 650	A3	Fuisz Technologies Ltd.	03-27-1996		
		EP	0 788 790	B1	Jagotec AG	05-19-2004		
		EP	0 834 516	B1	Kabushiki Kaisha Hayashibara Seibutsu Kagaku Kenkyujo	04-08-1998		
		EP	0 861 659	A1	University of Kentucky Research Foundation	09-02-1998		
		EP	0 950 402	B1	McNeil-PPC, Inc.	05-14-2003		
		EP	1 077 065	A1	Chugai Seiyaku Kabushiki Kaisha	02-21-2001		
		GB	866 681		May & Baker Ltd.	04-26-1961		
		GB	888 038		The Wander Company	01-24-1962		
		GB	936 386		The Wellcome Foundation Limited	09-11-1963		
		GB	994 742		The Wellcome Foundation Limited	06-10-1965		
		GB	1 144 915		Armour Pharmaceutical Company	03-12-1969		
		GB	1 372 040		Boehringer Ingelheim	10-30-1974		
		GB	1 464 388		Schering Aktien-Gesellschaft	02-09-1977		
		GB	1 510 772		ACO Lakemedel AB			
		GB	2 182 559	A	Alza Corporation	05-20-1987		

Examiner Signature		Date Considered	
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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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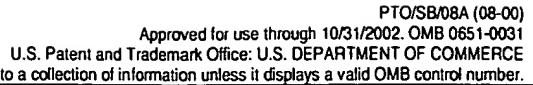
Sheet 6 of 7

<b>Application Number</b>	09/966,493
<b>Filing Date</b>	September 28, 2001
<b>First Named Inventor</b>	Joseph R. Luber
<b>Group Art Unit</b>	1615
<b>Examiner Name</b>	Robert Joynes
<b>Attorney Docket Number</b>	MCP-274

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>				
		GB	2 197 778	A	Katjes Fassin GmbH & Co. KG	06-02-1988		
		GB	2 284 760	A	Euroceltique S.A.	06-21-1995		
		NL	8602556		Alza Corporation	05-02-1988	English language translation attached	
		WO	94/06416	A1	Jagotec AG	03-31-1994		
		WO	94/07470	A1	Pfizer Inc.	04-14-1994		
		WO	95/02396	A1	Smithkline Beecham Corporation	01-26-1995		
		WO	97/06695	A1	The Procter & Gamble Company	02-27-1997		
		WO	98/20870	A1	Pozen Inc.	05-22-1998		
		WO	99/02136	A1	Peter Greither	01-21-1999	NOTE: English language abstract only	
		WO	99/32092	A1	Smithkline Beecham Corporation	07-01-1999		
		WO	99/51209	A1	Impax Pharmaceuticals, Inc.	10-14-1999		
		WO	99/56730	A1	Alza Corporation	11-11-1999		
		WO	00/18447	A2 & A3	Impax Pharmaceuticals, Inc.	04-06-2000		
		WO	00/25755	A1	Fuisz Technologies Ltd.	05-11-2000		
		WO	02/19833	A2 & A3	Akpharma Inc.	03-14-2002		

Examiner Signature		Date Considered	
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Substitute for form 1449A/PTO

(use as many sheets as necessary)

<i>Application Number</i>	09/966,493
<i>Filing Date</i>	September 28, 2001
<i>First Named Inventor</i>	Joseph R. Luber
<i>Group Art Unit</i>	1615
<i>Examiner Name</i>	Robert Joynes
<i>Attorney Docket Number</i>	MCP-274

Examiner Signature		Date Considered	
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**1 Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.**

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